



National Standards Authority of Ireland

IRISH STANDARD

I.S. EN 868-1:1997

ICS 11.080

55.040

**PACKAGING MATERIALS AND SYSTEMS
FOR MEDICAL DEVICES WHICH ARE TO BE
STERILIZED - PART 1: GENERAL
REQUIREMENTS AND TEST METHODS**

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Údarás um Chaighdeáin Náisiúnta na hÉireann

DECLARATION

OF

SPECIFICATION

ENTITLED

**PACKAGING MATERIALS AND SYSTEMS FOR MEDICAL DEVICES WHICH ARE TO
BE STERILIZED - PART 1: GENERAL REQUIREMENTS AND TEST METHODS**

AS

THE IRISH STANDARD SPECIFICATION FOR

**PACKAGING MATERIALS AND SYSTEMS FOR MEDICAL DEVICES WHICH ARE TO
BE STERILIZED - PART 1: GENERAL REQUIREMENTS AND TEST METHODS**

NSAI in exercise of the power conferred by section 16 (3) of the National Standards Authority of Ireland Act, 1966 (No. 28 of 1996) and with the consent of the Minister for Enterprise, Trade and Employment, hereby declares as follows:

1. This instrument may be cited as the Standard Specification (Packaging materials and systems for medical devices which are to be sterilized - Part 1: General requirements and test methods) Declaration, 1997.
2. (1) The Specification set forth in the schedule to this declaration is hereby declared to be the standard specification for Packaging materials and systems for medical devices which are to be sterilized - Part 1: General requirements and test methods. The Schedule comprises the text of EN 868-1:1997.
(2) The said standard specification may be cited as Irish Standard EN 868-1:1997 or as I.S. EN 868-1:1997.

EUROPEAN STANDARD

EN 868-1

NORME EUROPÉENNE

EUROPÄISCHE NORM

February 1997

ICS 11.080; 55.040

Descriptors: medical equipment, sterilisation, packing, specifications, operating requirements, compatibility, storage

English version

**Packaging materials and systems for medical
devices which are to be sterilized - Part 1: General
requirements and test methods**

Matériaux et systèmes d'emballages pour les
dispositifs médicaux devant être stérilisés -
Partie 1: Exigences générales et méthodes
d'essai

Verpackungsmaterialien und -systeme für zu
sterilisierende Medizinprodukte - Teil 1:
Allgemeine Anforderungen und Prüfverfahren

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Europäisches Komitee für Normung

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

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